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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,035	10/12/2000	Linda Gillian Durrant	0380-P02284U	5601

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06/18/2002

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EXAMINER

DAVIS, NATALIE A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/18/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,035

Applicant(s)

DURRANT ET AL.

Examiner

Natalie A. Davis

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 27-36 is/are pending in the application.
- 4a) Of the above claim(s) 13-15, 20-24 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16, 17, 19 and 27-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1642

DETAILED ACTION

Applicant's amendment filed 8 April 2002 (Paper No: 11) is acknowledged. Accordingly, claims 1, 2, 4-7, 13-14, 27, and 31-32 are amended, claim 3 is cancelled, and claims 33-36 are new. Claims 1-24, and 27-36 are pending and claims 1-12, 16-17, and 27-36 are under examination.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Applicant's traversal of the election of Group I, claims 1-12, 16-17, 19, and 27-32 is acknowledged. The traversal is on the ground(s) that the invention is broadly drawn to vaccines comprising polypeptides of the CD55 family, all the claims contain common technical features, and Durrant does not teach a vaccine based on the 791Tgp72 antigen per se but on an antibody with mimics it. This is not found persuasive for reasons indicated in the previous office action. Since Durrant suggest that 791Tgp72 may be used in a cancer vaccine, the invention as claimed does not have a special technical feature that defines a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-12, 16-17, 19, and 27-32 are being examined as belonging to the elected Group I, while claims 13-15, 20-24, and 26 are withdrawn from examination as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112 1st Maintained

2. Rejection of claims 1-12, 16-17, 19, 27-32 and new claims 33-36 under 35 U.S.C.112, first paragraph is maintained for reasons set forth in the previous office action. The traversal is on the grounds that a vaccine may be prophylactic or therapeutic, limitations of the claims exclusively to therapeutic vaccines, would be inappropriate, the specification contains ample disclosure for the effectiveness of the vaccines of the invention, and the fact that a fragment or derivative may have lost the 3D structure of the native CD55/791Tgp72 antigen is irrelevant to

Art Unit: 1642

its function. Applicant's arguments have been considered but are not persuasive. The invention as claimed is disclosed as a vaccine only capable of stimulating an immune response and there is no evidence indicating that it is sufficient to protect from developing cancer. Furthermore, the 3D structure of the fragments and/or derivatives is not relevant. The specification has not disclosed how one is to make and select for a fragment or derivative that is capable of functioning as contemplated. A derivative may encompass just about anything, an addition, subtraction, substitution of amino acids, the addition of functional groups, chemical modifications, etc., and the specification does not give any guidance to which fragments or derivatives will exhibit the biological activities as the claimed, or any guidance as to which regions of amino acid sequence are responsible for biological activity and thus, must be preserved so the molecule will function as claimed. Thus, it would be an undue burden to one of ordinary skill in the art to assay for claimed sequences, which are capable of functioning as contemplated.

New Claim Rejections - 35 USC § 112

3. Claims 4-7, 9, 27 and 30-32 are indefinite for making a reference to a figure in the specification. Claims are to be complete in themselves (MPEP 2173.05(s)). Incorporation by reference to a specific figure, table, experiment, etc. "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993)

4. Claims 1-12, 16-17, 19, 27-32 and new claims 33-36 are rejected under 35 U.S.C. 112, first paragraph. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Vas-Cath Inc. v. Mahurkar (CA FC) 19 USPQ2d 1111 (6/7/1991) clearly states that "written description" of invention required by first paragraph of 35 U.S.C. 112 is separate and

Art Unit: 1642

distinct from that paragraph's requirement of enabling disclosure, since description must do more than merely provide explanation of how to "make and use" invention; applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed. An applicant shows possession by describing the claimed invention with all its limitations using such descriptive means as words, structures, diagrams, and formulas. Also, description of an actual reduction to practice, or by showing the invention was "ready for patenting," or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention at the time of filing.


The specification does not reasonably provide written description for a cancer vaccine comprising a derivative of a fragment of a polypeptide or the CD55 family. The disclosure does not indicate that applicant had possession claimed derivative, as there is no actual reduction to practice, sufficient descriptive information, such as definitive structural features, which are critical to polypeptide activity, or complete detailed description of addition, subtraction, and/or substitution of amino acids, the addition of functional groups, or chemical modifications, etc. indicating that the claimed derivatives were indeed isolated, produced, and assayed for the uses disclosed. Thus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed fragments and derivatives.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD
June 8, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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